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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,729	12/08/2004	Takeshi Nakanishi	441P088	6032
42754 7590 02/26/2007 NIELDS & LEMACK 176 EAST MAIN STREET, SUITE 7 WESTBORO, MA 01581			EXAMINER ROGERS, JAMES WILLIAM	
			ART UNIT	PAPER NUMBER
			1618	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/26/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,729	NAKANISHI ET AL.	
	Examiner	Art Unit	
	James W. Rogers, Ph.D.	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2007.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendments to the claims filed 01/16/2007 have been entered. Any rejection/objection not addressed in the office action below have been withdrawn.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1,3-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yokoyama et al. (US 6,080,396) in view of Matsumara (Drug Delivery System, 16, No. 5, 401-408, 2001, disclosed as background art by applicants) in view of (JP-A No. 2001-226294, disclosed as background art by applicants), for the reasons set forth in the previous office action filed 10/11/2006.

Applicants arguments/remarks have been fully considered but are not considered persuasive.

Applicant asserts that Yokoyama lists but does not exemplify other solvents besides DMF as evidenced by the lack of working examples and one skilled in the art

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would have no reasonable expectation as to whether micelle formation is actually possible using other solvents.

The relevance of this assertion is unclear.

Clearly Yokoyama discloses that the solvent used can be DMF, dioxane, THF, water or a mixture thereof, certainly water/THF would satisfy applicants claimed mixed solvent of water and a low-boiling point organic solvent. Obviously one with skill in the art would expect success since water/low boiling solvents are already disclosed as useful within Yokoyama. The examples within Yokoyama were given solely for the purpose of illustration and were not to be construed as being limiting to their invention since many variations are possible without departing from the spirit and scope of the invention. Therefore since Yokoyama obviously discloses a solvent system of water/low boiling organic solvent the limitation is met.

Applicants asserts that Matsumara points out problems with dialysis and ultrafiltration but does not include any alternative.

The examiner agrees as noted in the previous office action, Matsumara was only used to show that it would have been obvious to the skilled artisan to use another technique to concentrate drugs instead of ultrafiltration and dialysis. '294 was used to show that producing a macromolecular block copolymer-drug composite by steps other than dialysis or ultrafiltration was already well known in the art.

Applicants assert that '293 uses chlorinated solvents which cannot be industrially used and that distilling off the water/organic solvent in a single phase is not disclosed. Because of the differences in solvents used one skilled in the art would not be

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motivated to eliminate the dialysis and ultrafiltration processes of Yokoyama and Sakurai in view of '294.

The relevance of these assertions is unclear. Firstly applicants do not claim an industrial process or that the solvent is comprised of one phase and their claims as currently amended do not preclude the use of halogenated solvents. The examiner does not consider "mixed solvent of water and a low-boiling point solvent" to be particularly limiting or preclude a two-phase solvent system. Secondly since the '294 reference is used as a secondary reference in combination with Yokoyama and Matsumara it does not have to disclose all of applicants claimed invention on its own. The examiner disagrees that there is no motivation to combine '294 with Yokoyama, clearly the motivation would stem from the disclosure of Matsumara stating that when dialysis or ultrafiltration are conducted on pharmaceuticals with contained drugs part of the drug is also removed, therefore one skilled in the art would seek other techniques to remove the solvent besides ultrafiltration or dialysis which is clearly disclosed within '294. The difference in the solvent systems is not considered to be a critical factor for teaching away since obviously chloroform and THF are both relatively low boiling and both references disclose the use of a mixture of organic solvent and water. One with skill in the art could obviously envision using the same technique for removing solvents with similar boiling points. It is especially obvious to combine methods of production for two references that are in the same field of endeavor; obviously '294 and Yokoyama are related as pertaining to methods to produce macromolecular block copolymer-drug composites.

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Claims 1,3-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakurai et al. (EP 0,397,307 A2) in view of Matsumara (Drug Delivery System, 16, No. 5, 401-408, 2001, disclosed as background art by applicants) in view of (JP-A No. 2001-226294, disclosed as background art by applicants), for the reasons set forth in the previous office action filed 10/11/2006.

Applicant appears to assert that there is no motivation to combine Sakurai with '294 because the micelle disclosed in Sakurai does not encapsulate a drug in its core as in '294 therefore the problems pointed out in Matsumara will not be encountered in Sakurai.

The relevance of this assertion is unclear. Clearly Matsumara discloses that when dialysis or ultrafiltration are conducted on pharmaceuticals with contained drugs part of the drug is also removed, it does not matter where the drug is located within the polymer for this effect to take place. '294 and Sakurai are obviously combinable they are related as pertaining to methods to produce macromolecular block copolymer-drug composites. Therefore in light of the arguments above the rejection stands.

Conclusion

No claims are allowed at this time.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

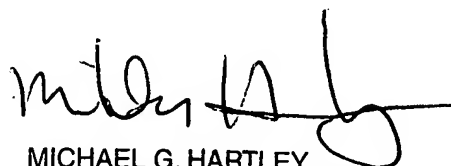
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 572-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER